

November 12, 2021

Submitted Electronically

The Honorable Xavier Becerra, Secretary Office of Population Affairs Office of the Assistant Secretary for Health U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, D.C. 20201

Re: Supplemental Evidence and Data Request on *Telehealth for Women* (86 FR 56708)

Dear Secretary Becerra,

On behalf of Americans United for Life (AUL), I am writing to provide supplemental data for the Evidence-based Practice Centers (EPC) Program's systematic review of *Telehealth for Women*. Although telemedicine generally is beneficial for women's health, telehealth abortion increases complications and opens the likelihood of misuse of abortion-inducing drugs. I write in opposition to expanding a telehealth option to women seeking chemical abortions.

AUL is the oldest and most active pro-life nonprofit advocacy organization in the country. Founded in 1971, before the Supreme Court's decision in *Roe v. Wade*, AUL has dedicated 50 years to advocating for comprehensive legal protections for human life from conception to natural death.

AUL has long advocated for women's health and safety in obtaining an abortion. AUL works towards this goal by drafting wide-ranging model legislation, including a comprehensive chemical abortion health and safety bill. AUL works extensively with state representatives to pass constitutional pro-life laws, and AUL attorneys regularly testify in the federal and state legislatures on pro-life issues. AUL files amicus briefs in key cases, including American College of Obstetricians and Gynecologists v. United States Food and Drug Administration, in which a lawsuit

¹ Abortion Inducing Drugs Information Act (Ams. United for Life 2021).

² See, e.g., The Texas Abortion Ban and its Devastating Impact on Communities and Families Before the H. Comm. On the Judiciary, 117th Cong. (2021) (testimony of Catherine Glenn Foster, President & CEO, Americans United for Life).

challenged the FDA in-person requirement for distribution of chemical abortion drugs.³ Supreme Court Justices have cited briefs authored by AUL in major abortion decisions.⁴

After reviewing the research protocol and scientific evidence, I have concluded that expanding a telehealth option for women seeking chemical abortions would increase women's health complications and unnecessarily risk misuse of abortion-inducing drugs. I urge the Department of Health and Human Services to explicitly exclude a telehealth option for chemical abortions.

I. Women Suffer Complications from Chemical Abortions.

The "chemical abortion pill" (also known as a "medical abortion") is a regimen of two drugs, mifepristone and misoprostol. According to the FDA label, the woman takes mifepristone first, most often at the clinic directly from a doctor or clinician. Mifepristone blocks the hormone progesterone, resulting in a breakdown of the uterine lining, ending the pregnancy. Several hours later she then takes misoprostol at home, which causes contractions and expulsion of the deceased fetus without medical involvement or supervision. Chemical abortion has risks, which is why the FDA only approved it with a Risk Evaluation and Mitigation Strategy (REMS), a drug safety program required for medications with serious safety concerns. In its 2016 review, the FDA determined that the REMS, which includes an in-person dispensing requirement, remained necessary.

Studies from Scandinavian countries, which record pregnancy and medical events more accurately than the United States due to their centralized record-keeping and single payor healthcare systems, give a better picture of chemical abortion complications than U.S. data. In a study of 42,619 Finnish women receiving chemical abortions up to nine weeks gestational age, the overall adverse events were

³ Brief *Amici Curiae* of 102 Members of Congress in Support of Defendant-Appellant FDA and Reversal of the Lower Court, *Am. Coll. of Obstetricians and Gynecologists v. U.S. Food and Drug Admin.*, No. 20-1784 (4th Cir. dismissed May 19, 2021).

⁴ See, e.g., Akron v. Akron Center for Reproductive Health, 462 U.S. 416, 426 n.9 (1983); Webster v. Reproductive Health Services, 492 U.S. 490, 530 (1989) (O'Connor, J., concurring in part and concurring in the judgment); June Medical Services L.L.C. v. Russo, 140 S. Ct. 2103, 2156 n.3 (2020) (Alito, J., dissenting).

⁵ Questions and Answers on Mifeprex, U.S. FOOD AND DRUG ADMIN. (Apr. 13, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex.

⁶ Highlights of Prescribing Information: Mifeprex, DANCO LAB'YS, LLC (Revised Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

⁷ Medical Abortion, MAYO CLINIC, www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687 (last visited Nov. 12, 2021).

 $^{^8}$ Mifeprex (mifepristone) Information, U.S. FOOD and Drug Admin. (Apr. 13, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

fourfold higher in chemical (20.0%) versus surgical abortions (5.6%).¹⁰ Women hemorrhaged more commonly after chemical abortion (15.6% compared with 2.1%).¹¹ They also had incomplete abortions more often in chemical abortions (6.7% versus 1.6%).¹² The rate of surgical (re)evacuation was higher after chemical abortions (5.9%) than surgical abortions (1.8%).¹³

Another study examined first and second trimester chemical abortions of 18,248 Finnish women. Women undergoing chemical abortions needed surgical evacuation in 9.9% of cases. Women specifically undergoing second trimester chemical abortions needed surgical evacuation in 39% of cases. Later in pregnancy, the likelihood of serious complications significantly increases, something that cannot be controlled for when pills are sent through the mail and taken at the woman's discretion.

In a systematic review of chemical abortions, one international study examined 47,283 women undergoing chemical abortions in optimal conditions up to nine weeks gestation. ¹⁷ Of these women, 4.8% had treatment failures. ¹⁸ The data showed ongoing pregnancies in 1.1% of cases. ¹⁹

A separate U.S.-based systematic review examined 33,846 women undergoing chemical abortions through ten weeks gestation.²⁰ As a best-case scenario, the study showed 3.4% of chemical abortions failed and required surgery.²¹ Of the total women, 0.8% had ongoing pregnancies.²²

In the United States, state reporting of adverse events from chemical abortion pills is voluntary, and the FDA limited adverse event reporting to only deaths in 2016. Even so, the FDA has received Mifeprex reports of 24 deaths, 4,195 adverse events,

¹⁰ Maarit Niinimaki et al., *Immediate Complications After Medial Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795, 795 (Oct. 2009).

 $^{^{11}}$ *Id*.

 $^{^{12}}$ *Id*.

 $^{^{13}}$ *Id*.

¹⁴ Maarit J. Mentula et al., *Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study*, 26 HUMAN REPROD. 927, 927 (Feb. 2011).

¹⁵ *Id*. at 929.

¹⁶ *Id*. at 931.

¹⁷ Elizabeth G. Raymond et al., First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review, 87 CONTRACEPTION 26, 26 (Jan. 2013).

 $^{^{18}}$ *Id*.

 $^{^{19}}$ *Id*.

²⁰ Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion:* A Systematic Review, 126 Obstetrics & Gynecology 12, 12 (July 2015).

 $^{^{21}}$ *Id*.

 $^{^{22}}$ *Id*.

1,042 hospitalizations (excluding deaths), 599 blood loss requiring transfusions, 412 infections, and 69 severe infections.²³

States have limited reporting requirements. Arkansas, Texas, and Missouri provide a limited snapshot of complications following chemical abortions. In Arkansas in 2020, forty out of the forty-five reported complications occurred following a chemical abortion (versus a surgical abortion).²⁴ The majority of these complications occurred in women undergoing their first abortion.²⁵

In Texas, out of 56,358 total induced abortions, 29,013 were chemical abortions. 26 Although there were 263 reported complications, the state does not sort the data by type of procedure. 27

Out of 112 total abortion complications in 2019, Missouri reported sixty-five medical abortion complications, even though only fifteen medical abortions occurred in the state.²⁸ Presumably, these complications occurred from women presenting in Missouri after receiving abortion-inducing drugs from out-of-state providers.

The evidence shows chemical abortions have a greater risk of complications than surgical abortion. For the following reasons, telemedicine will only exacerbate this risk.

II. Chemical abortion requires an in-person physician consultation.

The use of telemedicine in chemical abortions would destroy necessary safeguards for women's health and safety. Last year, 102 members of Congress advocated against the use of telemedicine in chemical abortions, citing concerns over women's health complications and the risk of domestic violence. Even with health concerns and social distancing measures during the COVID-19 pandemic, the Supreme Court permitted the FDA's in-person chemical abortion dispensing requirement to remain in effect. On the safety of the safet

Simply put, chemical abortions require in-person visits with healthcare providers. In fact, the Mayo Clinic states that: "Medical abortion isn't an option if you . . . [c]an't make follow-up visits to your doctor or don't have access to emergency

 26 Tex. Health and Human Servs., 2020 Selected Characteristics of Induced Terminations of Pregnancy (rev. Oct. 2020).

²³ Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2018, U.S. FOOD AND DRUG ADMIN, https://www.fda.gov/media/112118/download.

 $^{^{24}}$ CENTER FOR HEALTH STAT., ARK. DEP'T OF HEALTH, INDUCED ABORTION COMPLICATIONS REPORT 6 (Jan. $2020 - \text{Dec.}\ 2020$).

²⁵ *Id*. at 8.

 $^{^{27}}$ Tex. Health and Human Servs., 2020 Complications of Induced Terminations of Pregnancy (Aug. 2021).

²⁸ Mo. Dep't of Health and Senior Servs., Missouri Vital Statistics 2019 50 (Nov. 2020).

²⁹ Brief Amici Curiae, Am. Coll. of Obstetricians and Gynecologists, No. 20-1784.

³⁰ Food and Drug Admin. v. Am. Coll. of Obstetricians and Gynecologists, 141 S. Ct. 578 (2021).

care."³¹ Medical institutions are in agreement about this; according to the world-renowned University of California-San Francisco Health Center, "a medical abortion involves at least two visits to a doctor's office or clinic."³² Follow-up visits and reporting are critical to ensure that if a woman has retained tissue, she gets the follow-up care she needs.

But even before a chemical abortion, healthcare providers must confirm a woman is a medically appropriate candidate for chemical abortion.³³ A number of medical conditions make a women ineligible to take the chemical abortion pill, including having a potentially dangerous ectopic pregnancy (a pregnancy outside of the uterus) or having an intrauterine device (IUD) in place.³⁴ Chemical abortion cannot terminate an ectopic pregnancy and should not be used after the first seventy days of pregnancy due to heightened risk to the woman's health.³⁵ The FDA requires certain healthcare provider qualifications, including the [a]bility to assess the duration of pregnancy accurately and the "[a]bility to diagnose ectopic pregnancies."³⁶ Mayo Clinic indicates that a physician can only diagnose an ectopic pregnancy by blood tests and an ultrasound.³⁷ In other words, a physician cannot determine via telemedicine whether a pregnancy is ectopic.

Determining gestational age usually is done in-person by ultrasound. Ultrasound is the most accurate method to establish or confirm gestational age in the first trimester. ³⁸ Dating a pregnancy by using a woman's last menstrual period(LMP) is less accurate. The American College of Obstetricians and Gynecologists (ACOG) indicates only one half of women accurately recall their LMP. ³⁹ In one study, forty percent of women had more than a five-day discrepancy between their LMP dating and the ultrasound dating. ⁴⁰ In this regard, LMP dating is not as precise as an ultrasound. But an accurate measurement of gestational age is required to show that a woman is even a candidate for a chemical abortion.

Without an in-person evaluation, abortion providers also cannot test for Rh

³¹ Medical Abortion, supra note 7.

³² Medical Abortion, UNIV. OF CAL. SAN FRANCISCO, UCSF HEALTH,

www.ucsfhealth.org/treatments/medical-abortion (last visited Nov. 12, 2021).

³³ In most states, this consultation is with a physician. In a few states, like California, it can be done by a midlevel provider, such as a nurse practitioner, certified nurse-midwife, or physician assistant. STEVEN H. ADEN, DEFENDING LIFE: EVERYONE COUNTS 2020 45 (Ams. United for Life, 2020 ed. 2019).

³⁴ Questions and Answers on Mifeprex, supra note 5.

³⁵ **I**d

 $^{^{36}}$ Prescriber Agreement Form: Mifeprex (Mifepristone), U.S. Food and Drug Admin. (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-

²⁹_Prescriber_Agreement_Form.pdf.

³⁷ Ectopic Pregnancy, MAYO CLINIC (Dec. 18, 2020), https://www.mayoclinic.org/diseases-conditions/ectopic-pregnancy/diagnosis- treatment/drc-20372093.

³⁸ COMM. ON OBSTETRIC PRACTICE AM. INST. OF ULTRASOUND IN MED. SOC'Y FOR MATERNAL-FETAL MEDICINE, *Methods for Estimating the Due Date*, Comm. Op. No.700, at 1 (May 2017). ³⁹ *Id.* at 2.

 $^{^{40}}$ *Id*.

negative blood type. During pregnancy, if a woman has Rh negative blood while her fetus is Rh positive, the woman's body may produce antibodies after exposure to fetal red blood cells. Abortion can cause maternal exposure to fetal blood, even in the first trimester. Therefore, if indicated, a healthcare provider must give a woman with Rh negative blood an Rh immuneglobulin injection. Without the injection, antibodies can damage future pregnancies by creating life-threatening anemia in fetal red blood cells. ACOG describes that Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated. ARh negative blood typing is thus a medically necessary test, but it cannot occur during medical abortions that are done entirely via telemedicine.

III. Telehealth Chemical Abortions Cannot Properly Screen for Domestic Abuse.

Intimate partner violence (IPV) and reproductive control are domestic violence concerns for women seeking an abortion. IPV includes physical violence, sexual violence, stalking, and psychological aggression by a current or former intimate partner. The Centers for Disease Control and Prevention (CDC) notes that "IPV is a significant public health issue that has many individual and societal costs." Heart, digestive, reproductive, muscle and bones, and nervous systems. IPV survivors may experience depression and post-traumatic stress disorder. Survivors also are at higher risk for engaging in healthrisk behaviors, such as smoking, binge drinking, and sexual risk behaviors. The CDC estimates the lifetime medical, lost work productivity, and criminal justice costs are \$3.6 trillion. The lifetime cost for a female victim of IPV is \$103,767. Thus, there are steep individual and societal costs for IPV.

Unfortunately, IPV is common.⁵¹ One in four women have experienced IPV.⁵² Nearly one in five women have experienced severe physical violence by an intimate partner.⁵³ "Unintended" pregnancy, which may be a reason to seek an abortion, raises

 $^{^{41}}$ Rh Factor Blood Test, MAYO CLINIC (June 17, 2020), https://www.mayoclinic.org/tests-procedures/rh-factor/about/pac-20394960.

 $^{^{42}}$ *Id*.

⁴³ *Id*.

⁴⁴ COMM. ON PRACTICE BULLETINS – GYNECOLOGY AND THE SOC'Y OF FAMILY PLANNING, *Medication Abortion Up to 70 Days of Gestation*, Comm. Op. 225, at 40 (Oct. 2020).

 $^{^{45}}$ Preventing Intimate Partner Violence, CTRS. FOR DISEASE CONTROL AND PREVENTION (Nov. 2, 2021), https://www.cdc.gov/violenceprevention/intimatepartnerviolence/fastfact.html.

 $^{^{46}}$ Id.

 $^{^{47}}$ Id.

 $^{^{48}}$ *Id*.

 $^{^{49}}$ *Id*.

 $^{^{50}}$ *Id*.

 $^{^{51}}$ *Id*.

⁵² Id.

 $^{^{53}}$ *Id*.

the risk of IPV. Women with unintended pregnancies are four times as likely to experience IPV as women with intended pregnancies.⁵⁴ Notably, half of all pregnancies are characterized as "unintended".⁵⁵

Abortion also increases the risk of IPV. There are "[h]igh rates of physical, sexual, and emotional IPV . . . among women seeking a[n abortion]."⁵⁶ For women seeking abortion, the prevalence of IPV is nearly three times greater than women continuing a pregnancy.⁵⁷ Post-abortive IPV victims also have a "significant association" with "psychosocial problems including depression, suicidal ideation, stress, and disturbing thoughts."⁵⁸

Notably, a survey in the American Journal of Public Health indicated IPV perpetrators are more likely than non-abusive men to be involved in a pregnancy that ended in abortion.⁵⁹ The surveyed male IPV perpetrators were likely to be in conflict with their female partner particularly over her abortion decision when the violence occurred.⁶⁰

With the prevalence of IPV, ACOG acknowledges that "[b]ecause of the known link between reproductive health and violence, health care providers should screen women and adolescent girls for intimate partner violence and reproductive and sexual coercion at periodic intervals." Intimate partner violence is therefore a grave concern for women seeking abortion.

Reproductive control, which overlaps IPV, is also a public policy concern for women seeking abortion. Reproductive control describes "actions that interfere with a woman's reproductive intentions." Reproductive control occurs over "decisions around whether or not to start, continue or terminate a pregnancy, including deployment of contraception, and may be exercised at various times in relation to intercourse, conception, gestation and delivery." Reproductive control includes intimate partners, family members, and sex traffickers asserting control over a

 $^{^{54}}$ COMM. ON HEALTHCARE FOR UNDERSERVED WOMEN, $Reproductive\ and\ Sexual\ Coercion,$ Comm. Op. No.554, at 2 (Feb. 2013) (internal citation omitted).

⁵⁵ COMM. ON GYNECOLOGIC PRACTICE LONG-ACTING REVERSIBLE CONTRACEPTION WORKING GROUP, Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy, Comm. Op. No. 645, at 1 (reaffirmed 2018).

⁵⁶ Megan Hall et al., Associations Between Intimate Partner Violence and Termination of Pregnancy: A Systematic Review and Meta-Analysis, 11 PLoS Med. 1, 15 (Jan. 2014).

⁵⁷ Reproductive and Sexual Coercion, supra note 54, at 2.

⁵⁸ Hall, *supra* note 56, at 11.

⁵⁹ Jay G. Silverman et al., *Male Perpetration of Intimate Partner Violence and Involvement in Abortions and Abortion-Related Conflict*, 100 Am. J. of Pub. Health 1415, 1416 (Aug. 2010).

⁶¹ Reproductive and Sexual Coercion, supra note 54, at 1.

 ⁶² Sam Rowlands & Susan Walker, Reproductive Control by Others: Means, Perpetrators and Effects,
45 BMJ SEXUAL & REPROD. HEALTH 61, 62 (2019).
⁶³ Id.

woman's reproductive decisions.⁶⁴ In the context of abortion, reproductive control not only produces coerced abortions or continued pregnancies, it also affects whether the pregnancy was intended in the first place.⁶⁵

Reproductive control is a prevalent issue for women. "As many as one-quarter of women of reproductive age attending for sexual and reproductive health services give a history of ever having suffered [reproductive control]." In the United States, African-American and multiracial women disproportionately experience reproductive control. Vounger women also are more at risk for reproductive control. Coerced abortion particularly is a problem for victims, including minor victims, of sex trafficking in the United States.

Women seeking abortion are susceptible to domestic violence in the forms of IPV and reproductive control. In turn, IPV and reproductive control may impair a woman's ability to provide consent to an abortion. Telemedicine only reduces the safeguards against domestic violence and coercion.

ACOG recommends "Screen[ing] for IPV in a private and safe setting with the woman alone and not with her partner, friends, family, or caregiver." 70 Yet, telemedicine cannot ensure that a coercive partner, friend, family member, or caregiver is not in the room with a woman seeking a chemical abortion.

The COVID-19 pandemic highlights the issue of telemedicine and domestic abuse. The American Medical Association describes:

While social distancing and quarantine measures are in place to protect the general public, domestic violence situations are likely to worsen as victims may be limited in seeking care or leaving the unsafe situation. Domestic violence is also a contributing factor to adverse health outcomes such as increased risk of chronic disease, depression, post-traumatic stress disorder, and substance use behaviors.⁷¹

ACOG echoes the concern of COVID-19's impact on domestic violence. According to ACOG, "There have been reports of the exacerbation of intimate partner violence

⁶⁴ *Id*. at 65.

⁶⁵ *Id*. at 61–62.

⁶⁶ *Id*. at 62.

 ⁶⁷ Charvonne N. Holliday et al., Racial/Ethnic Differences in Women's Experiences of Reproductive Coercion, Intimate Partner Violence, and Unintended Pregnancy, 26 J. OF WOMEN'S HEALTH 828 (2017).
⁶⁸ Elizabeth Miller et al., Recent Reproductive Coercion and Unintended Pregnancy Among Female Family Planning Clients, 89 CONTRACEPTION 122 (2014).

⁶⁹ Rowlands, *supra* note 62, at 64.

 $^{^{70}}$ COMM. ON HEALTH CARE FOR UNDERSERVED WOMEN, *Intimate Partner Violence*, Comm. Op. No. 518, at 3 (Feb. 2012).

⁷¹ COVID-19 Resource Guide: Women in Medicine, Am. Med. Ass'n (Aug. 3, 2020), https://www.ama-assn.org/practice-management/physician-health/covid-19-resource-guide-women-medicine.

during the COVID-19 pandemic. The severity of intimate partner violence may escalate during pregnancy or the postpartum period."⁷² Notably, ACOG recommends healthcare providers screen patients multiple times because patients may not be able to disclose abuse each time they are screened.⁷³ In other words, domestic violence screening by telehealth "may not allow individuals the privacy or safety needed to disclose abuse."⁷⁴ Thus, telehealth ineffectively screens women seeking chemical abortions for domestic violence or coercion. If she changes her mind, no medical professional is there to help her. She is left alone to care for her physiological and psychological health, as well as her safety if complications or IPV arise.

IV. Conclusion

For the forgoing reasons, I urge the Department to explicitly exclude abortion from any telehealth rules it enacts, now or in the future.

Sincerely,

Carolyn McDonnell, Esq. Staff Counsel AMERICANS UNITED FOR LIFE

⁷² COVID-19 FAQs for Obstetrician-Gynecologists, Obstetrics, AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS (rev. July 1, 2021), https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-obstetrics.

⁷³ *Id.*; see also *Intimate Partner Violence*, supra note 70, at 3 (noting IPV screening should occur periodically and "at various times…because some women do not disclose abuse the first time they are asked).

⁷⁴ COVID-19 FAQs for Obstetrician-Gynecologists, supra note 72.